



Visiting the AADAP Website

An Online Demonstration

presented
by

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U.S. Fish and Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Bozeman, Montana



AADAP Website Tour



A screenshot of the AADAP website displayed in a Windows Internet Explorer browser window. The address bar shows the URL: <http://www.fws.gov/fisheries/aadap/home.htm>. The browser's search bar contains the text "Google". The website header features the U.S. Fish & Wildlife Service logo and a large image of a fish. Below the header, the text "U.S. Fish & Wildlife Service" and "AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP (AADAP) PROGRAM" is displayed. A navigation menu is highlighted with a green oval, containing the following links: "About Us", "Whats Shakin'", "Newsletters", "NADAs", "INAD Program", "JSA Research Forum", "Study Summaries", "AADAP Summary", "National INAD Program", "Drug Research Program History", "AADAP Staff", and "AADAP Fact Sheets". A hand cursor is pointing at the "AADAP Staff" link. Below the navigation menu, the website is divided into three main sections: "WHAT'S SHAKIN'", "IN STATEMENT", and "HOT TOPICS". The "WHAT'S SHAKIN'" section includes a "GENERAL NEWS" link. The "IN STATEMENT" section contains the text: "The Aquatic Animal Drug Approval Partnership (AADAP) Program is a broad, partnership-based program of national scope located in". The "HOT TOPICS" section features a headline: "CVM Publishes Proposed MUMS 'Indexing' Regs" and a sub-headline: "The second of a series of features of".



AADAP Website Tour



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INAD INFORMATION

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Chloramine - T
Florfenicol
AQUI-S®
Diquat
SE-MARK®
LHRHa
Common Carp Pituitary
Oxytetracycline Immersion
Oxytetracycline Injectable
Oxytetracycline Bath...
17- α methyltestosterone

Pictured left to right:
Bonnie Johnson, Dan Carty, Miranda Dotson,
Jim Bowker, Molly Bowman, Tom Bell and Dave Erdahl

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Jim Bowker; Research Program Manager
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AADAP Website Tour



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http://www.fws.gov/fisheries/aadap/home.htm

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AADAP

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AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP (AADAP) PROGRAM

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Background Information and News | Subject Expert Directory | Example Protocols and SOPs | Meeting Notes

AADAP
Aquatic Animal Drug Approval
Partnership Program

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WHAT'S SHAKIN'

GENERAL NEWS

MISSION STATEMENT

The Aquatic Animal Drug Approval Partnership (AADAP) Program is a broad, partnership-based program of national scope located in

HOT TOPICS

CVM Publishes Proposed MUMS "Indexing" Regs


The second of a series of features of



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[Oxytetracycline Immersion](#)
[Oxytetracycline Injectable](#)
[Oxytetracycline Bath...](#)

Example Protocols and Standard Operating Procedures...

The purpose of this page is to make available technical information, e.g., Standard Operating Procedures (SOPs) and protocols, produced and used by researchers involved in the NADRF. Please use these documents only as guidance or templates, and contact the appropriate facility with any questions.

Technical Sections

[Efficacy - Protocols and Associated SOPs](#)
[Target Animal Safety - Protocols and Associated SOPs](#)
[Human Food Safety - Protocols and Associated SOPs](#)
[Environmental Safety - Protocols and Associated SOPs](#)
[Antimicrobial Safety - Protocols and Associated SOPs](#)

Standard Operating Procedures (SOPs)

[General SOPs - SOPs](#)
[Instrument - SOPs](#)
[Technical SOPs - SOPs](#)
[Protocol-specific SOPs - see the specific Technical Section protocol \(above\)](#)



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WHAT'S SHAKIN'

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INAD INFORMATION

- Oxytetracycline Med. Feed

Studies in Support of New Animal Drug Approvals...

Studies submitted to FDA's Center for Veterinary Medicine




Other 'Quick & Dirty' preliminary studies...(coming soon)



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[AQUI-S®](#)

AQUI-S Studies...

Status of AQUI-S Efficacy Studies

We are almost finished with AQUI-S® pivotal and supportive studies required to complete the efficacy technical section for all freshwater reared fish. In order to complete this technical section, CVM's Aquaculture Team requires acceptance of 2-3 pivotal studies and 3-6 supportive studies on representative cold, cool, and warmwater fish species. Listed below is the status of these studies, please click on a species to see the abstract for that Final Study Report that has been submitted to CVM. Information last updated: 25 August 2006

Pivotal Studies

Coldwater

[rainbow trout: accepted by CVM](#)

[kokanee salmon: accepted by CVM \(study #1\)](#)

[kokanee salmon: accepted by CVM \(study #2\)](#)

[chinook salmon: accepted by CVM \(study #1\)](#)

[chinook salmon: accepted by CVM \(study #2\)](#)

Coolwater

[shovelnose sturgeon: accepted by CVM](#)



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WHAT'S SHAKIN'

GENERAL NEWS

North Carolina State University holds Fish Health Management class to be held in October at the NC State Veterinary Medicine campus, Raleigh, NC. [More...](#)

CVM Issues Proposed Regulations on MUMS Indexing:

MISSION STATEMENT

The Aquatic Animal Drug Approval Partnership (AADAP) Program is a broad, partnership-based program of national scope located in Bozeman, Montana. The mission of the AADAP Program is:

"Working with our partners to conserve, protect, and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration (FDA) approval

HOT TOPICS

CVM Publishes Proposed MUMS "Indexing" Regs


The second of a series of features of the Minor Use and Minor Species Animal Health Act of 2004, drug indexing, is one step closer to being implemented

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Drug-use Guidance...

- [General Information](#)
- [Approved Drugs](#)
- [Low Regulatory Priority \(LRP\) Drugs](#)
- [Generally Recognized as Safe \(GRAS\) Substances](#)
- [Forbidden Drugs](#)
- [FDA Deferred Decision](#)
- [Guidance Documents](#)
- [Veterinary Feed Directive Drugs](#)
- [EPA's Aquaculture Effluent Guidelines](#)
- [JSA's "Guide to Drug, Vaccine, & Pesticide Use in Aquaculture" \(Jan 2004 Revision\)](#)





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- Common Carp Pituitary
- Oxytetracycline Immersion
- Oxytetracycline Injectable
- Oxytetracycline Bath...
- 17-a methyltestosterone
- Formalin
- Potassium Permanganate
- Copper Sulfate
- Ovaplant®

GENERAL NEWS

North Carolina State University holds Fish Health Management course: The class is to be held 12-14 October at the NC State Vet Medicine campus, Raleigh, NC. [More...](#)

CVM Issues Proposed Regulations on MUMS Indexing: The second of a series of features of the Minor Use and Minor Species Animal Health Act of 2004, drug indexing, is one step closer to being implemented. [More...](#)

CVM Names New Director of the Office of Minor Use and Minor Species (OMUMS): In preparation for Dr. Andy Beaulieu's January 2007 retirement as the Director of OMUMS, Dr. Burnadette Dunham has been named to assume Dr. Beaulieu's role. [More...](#)

2006 Drug Approval Coordination Workshop: This year's annual Workshop was held in La Crosse, Wisconsin on 1-2 August 2006. [More...](#)

Program is a broad, partnership-based program of national scope located in Bozeman, Montana. The mission of the AADAP Program is:

"Working with our partners to conserve, protect, and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration (FDA) approval for drugs, chemicals, and therapeutants needed in aquaculture and fisheries management programs."

Public and private aquaculture in the United States has struggled for many years because of a severe shortage of FDA approved drugs and therapeutants for use in aquatic species. This situation has jeopardized the health and fitness of aquatic species held in captivity, many of which are key to restoration, recovery, and management activities by the FWS and its many partners. New aquatic animal drug approvals will benefit Federal, State, Tribal and private aquaculture programs alike throughout the United States.

The second of a series of features of the Minor Use and Minor Species Animal Health Act of 2004, drug indexing, is one step closer to being implemented

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AADAP Website Tour



Fact Sheet: Florfenicol INAD 10-697

for detailed information, see INAD study protocol, use link on the left

Browse other INAD Drugs

The following links are specific to:
Florfenicol

[Drug summary & history](#)

[Drug forms to be completed](#)

[Generic examples of completed forms](#)

[INAD study protocol](#)

[Material Safety Data Sheet \(MSDS\)](#)

[Study Summaries](#)

[What's the status of this drug's approval](#)

[Print this drug fact sheet](#)

[Print all drug fact sheets](#)

[INAD signup form \(Federal facilities\)](#)

[INAD signup form \(other facilities\)](#)

[Information on EPA's National Pollutant Discharge Elimination System \(NPDES\) Permits](#)

Objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of florfenicol to control mortality caused by certain bacterial diseases.
Drug name:	Florfenicol (Aquaflor™)
Source of drug:	Schering-Plough Animal Health
Address:	1095 Morris Avenue Union, NJ 07083-1982
Contact:	Dr. Richard Endris Phone: 908-473-3133; Fax: 908-629-3654; email: richard.endris@spcorp.com
Target pathogen(s):	Bacterial pathogens susceptible to florfenicol.
Method of administration:	Medicated-feed treatment
Treatment dosage:	10 milligrams florfenicol per kilogram fish body weight per day
Treatment regimen:	10 days (consecutive)
Withdrawal period:	21 days (all salmonids)
	28 days (all non-salmonids)
	No withdrawal period is required for fish that are not susceptible to legal harvest for a period of 28 days post-treatment.
Required test parameters:	Investigator must collect mortality data throughout the 5-day pre-treatment, treatment, and 21-day post-treatment period. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use:	Investigator must follow all instructions in the Study Protocol for INAD 10-697 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.
	Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	\$400.00 per facility per year
AADAP contact for other information:	Ms. Bonnie Johnson, FWS - AADAP Phone: 406-587-9265 ext. 136 Fax: 406-582-0242 bonnie_johnson@fws.gov